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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/624,395	07/24/2000	Keiko Neriishi	Q58690	6421

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EXAMINER	
FORMAN, BETTY J	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/624,395	NERIISHI, KEIKO	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

FINAL ACTION

1. This action is in response to papers filed 24 April 2003 in which claims 7 and 11-17 were amended. All of the amendments have been thoroughly reviewed and entered. The previous objections to the specification and rejections in the Office Action dated 24 January 2002 under 35 U.S.C. 112, first paragraph are withdrawn in view of the amendments. The previous rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) are maintained. All of the arguments have been thoroughly reviewed and are discussed below.

Claims 7-20 are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 7, 8, 10 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Shiraishi et al. (U.S. Patent No. 4,617,468, issued 14 October 1986). The claims are drawn to a microarray comprising a stimulable phosphor sheet and multiple kinds of biomolecules arrayed and fixed on the phosphor sheet in a known configuration. The claims are given the

broadest reasonable interpretation consistent with the indefinite claim language and the specification wherein it is unclear how the biomolecules are affixed on or within the phosphor layer wherein the microarray is defined as having "broad meanings embracing.... a macro array" (page 1, lines 14-16). Furthermore, the newly added phrase "consisting essentially of" is interpreted as equivalent to "comprising" following guidance provided in the MPEP.

> For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also In re Janakirama-Rao, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. (see MPEP 2111.03 and 2163).

Regarding Claim 7, Shiraishi et al. disclose a microarray comprising a stimulable phosphor layer on a substrate wherein said phosphor layer has affixed thereto an array of biomolecules (Column 5, lines 53-65 and Column 13, lines 26-35) and wherein the location of biomolecules is known (i.e. location information indicating the shape and position of the biomolecules is obtained (Column 16, lines 25-33) thereby obtaining the array as claimed.

Regarding Claim 8, Shiraishi et al. disclose a microarray comprising a stimulable phosphor layer on a substrate and a protective layer on the phosphor layer wherein the protective layer has affixed thereto an array of biomolecules (Column 12, line 67-Column 13, line 10) and wherein the location of biomolecules is known (i.e. location information indicating the shape and position of the biomolecules is obtained (Column 16, lines 25-33) thereby obtaining the array as claimed.

Regarding Claim 10, Shiraishi et al. disclose the microarray wherein the biomolecule is an oligonucleotide (Column 13, lines 26-30).

Regarding Claim 13, Shiraishi et al. disclose a microarray comprising a stimulable phosphor layer on a substrate wherein said phosphor layer has affixed thereto an array of detecting bodies (Column 5, lines 53-65 and Column 13, lines 26-35) and wherein the location of biomolecules is known (i.e. location information indicating the shape and position of the biomolecules is obtained (Column 16, lines 25-33) thereby obtaining the array as claimed.

Regarding Claim 14, Shiraishi et al. disclose a microarray comprising a stimulable phosphor layer on a substrate and a protective layer on the phosphor layer wherein the protective layer has affixed thereto an array of detecting bodies (Column 12, line 67-Column 13, line 10) and wherein the location of biomolecules is known (i.e. location information indicating the shape and position of the biomolecules is obtained (Column 16, lines 25-33) thereby obtaining the array as claimed.

Regarding Claim 15, Shiraishi et al. disclose the microarrays of Claims 7, 8, 13 and 14 wherein the substrate is polyester (Column 7, lines 36-41).

Response to Arguments

4. Applicant comments that the amendments "consisting essentially of" limits the microarray such that they no longer encompass components that have a material effect on the basis and novel characteristics of the invention such as the gel matrix of Shiraishi et al. The argument has been considered but is not found persuasive because as stated above, the phrase "consisting essentially of" is interpreted as "comprising" following guidance of the MPEP.

Furthermore, the argument is not found persuasive because the claims are drawn to an array wherein affixed on (or within) a phosphor layer is an array of biomolecules. Shiraishi teaches an array comprising a stimulable phosphor layer wherein affixed on the phosphor layer via an electrophoretic gel is an array of biomolecule as claimed (Column 5, lines 59-65). It is noted that Shiraishi does not teach the biomolecules are affixed within the phosphor layer. However, the claims are drawn in the alternative to being affixed on or within the phosphor layer. Because Shiraishi teaches affixed on the phosphor layer, they teach the array as claimed.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 11, 12 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiraishi et al. (U.S. Patent No. 4,617,468, issued 14 October 1986) in view of Davis et al. (Basic Methods in Molecular Biology, "DNA Hybridization", 1986, pages 84-87).

Regarding Claims 11, 12, 16 and 17, Shiraishi et al. teach a method for analyzing a biomolecule (Claims 11 & 12) and a sample (Claims 16 & 17) comprising: preparing a microarray comprising a stimulable phosphor layer and/or the protective layer wherein the stimulable phosphor layer has arrayed and affixed thereto an array of biomolecules/detecting bodies (i.e. labeled molecules e.g. proteins and nucleic acids); causing the stimulable phosphor sheet to store energy from the energy generating substance with which the fixed biomolecule is labeled; exposing the stimulable phosphor sheet to stimulating rays which cause the phosphor sheet to emit light in proportion to the amount of energy stored thereon and photoelectrically detecting the emitted light to detect the labeled biomolecule (Column 13, line 41-Column 14, line 5 and Column 14, line 49-Column 15, line 32) and wherein the biomolecules are in a

known configuration (i.e. location information indicating the shape and position of the biomolecules is obtained (Column 16, lines 25-33) thereby obtaining the array as claimed.

Shiraishi et al. teach the biomolecule is labeled and they teach providing the label by known methods (Column 13, lines 26-40) but they do not specifically teach labeling the fixed biomolecule by hybridization with a labeled biomolecule. However, labeling a biomolecule by hybridization with a labeled biomolecule was well known in the art at the time the claimed invention was made as taught by Davis et al. Specifically, Davis et al. teach hybridizing a labeled biomolecule with a biomolecule fixed on a support (page 85). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the labeling of Shiraishi et al. wherein all of the arrayed and fixed biomolecules are radioactively labeled with the labeling taught by Davis et al. wherein only biomolecular probes are labeled and wherein the labeled probes hybridize to specific arrayed biomolecules to thereby detect only specific biomolecule(s) and based on the known hazards of radioactive labels, label biomolecular-specific probes and hybridizing the probes to the arrayed biomolecules thereby reducing the number of radio-labeled biomolecules and reducing non-specific detection for the expected benefit of reduced biohazard risk and increased biomolecule-specific detection.

Regarding Claim 18, Shiraishi et al. the methods of Claims 11, 12, 16 and 17 wherein the substrate is polyester (Column 7, lines 36-41).

Regarding Claim 19, Shiraishi et al. teach the methods of Claims 11 and 12 wherein the biomolecule is an oligonucleotide (Column 13, lines 26-30).

Response to Arguments

7. Applicant comments on page 11, that in view of the previous comments and the amendments, Shiraishi does not render the claims obvious. Applicant further asserts that Shiraishi and Davis et al, alone or in combination do not teach or suggest fixation or within the phosphor layer. The arguments have been considered but are not found persuasive for the reasons stated above i.e. the open claim language encompasses the teaching of Shiraishi.

8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shiraishi et al. (U.S. Patent No. 4,617,468, issued 14 October 1986) in view of Heller et al (U.S. Patent No. 5,632,957, issued 27 May 1997).

Regarding Claim 9, Shiraishi et al a microarray comprising a stimulable phosphor layer on a substrate and a protective layer on the phosphor layer wherein the protective layer has affixed thereto an array of biomolecules (Column 12, line 67-Column 13, line 10) wherein the biomolecules are in a known configuration (i.e. location information indicating the shape and position of the biomolecules is obtained (Column 16, lines 25-33) thereby obtaining the array as claimed. Shiraishi et al further teach the microarray wherein the protective layer comprises polyacrylamide (Column 12, lines 13-20) and the biomolecules are affixed by electrophoretic resolution using "well known" methods (Column 13, lines 36-40) but they do not specifically teach the protective layer comprises poly-l-lysine. However, electrophoretic resolution on polyacrylamide comprising poly-l-lysine was well known in the art at the time the claimed invention was made as taught by Heller et al (Column 17, lines 54-65). Specifically, Heller et al teach a similar microarray comprising biomolecules arrayed and affixed to a polyacrylamide protective layer (Column 5, lines 3-8) wherein the surface of the polyacrylamide is functionalized with poly-l-lysine to thereby provide for covalent attachment of biomolecules to the surface (Column 18, lines 5-10). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the surface modification taught by Heller et al to the polyacrylamide surface of Shiraishi et al to thereby provide for covalent attachment of the biomolecules. One skilled in the art would have been motivated to covalently attach the biomolecules of Shiraishi et al to thereby provide stable, specific and localized

biomolecule binding for the expected benefit facilitating detection and analysis of the biomolecule and its interactions.

Response to Arguments

9. Applicant reiterates the arguments regarding Shiraishi and further asserts that Heller et al do not teach or suggest fixation or within the phosphor layer. The arguments have been considered but are not found persuasive for the reasons stated above.

10. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shiraishi et al. (U.S. Patent No. 4,617,468, issued 14 October 1986) in view of Davis et al. (Basic Methods in Molecular Biology, "DNA Hybridization", 1986, pages 84-87) as applied to Claim 12 above and further in view of Heller et al (U.S. Patent No. 5,632,957, issued 27 May 1997).

Regarding Claim 20, Shiraishi et al. teach a method for analyzing a biomolecule (Claims 11 & 12) and a sample (Claims 16 & 17) comprising: preparing a microarray comprising a stimulable phosphor layer and/or the protective layer wherein the stimulable phosphor layer has arrayed and affixed thereto an array of biomolecules/detecting bodies (i.e. labeled molecules e.g. proteins and nucleic acids); causing the stimulable phosphor sheet to store energy from the energy generating substance with which the fixed biomolecule is labeled; exposing the stimulable phosphor sheet to stimulating rays which cause the phosphor sheet to emit light in proportion to the amount of energy stored thereon and photoelectrically detecting the emitted light to detect the labeled biomolecule (Column 13, line 41-Column 14, line 5 and Column 14, line 49-Column 15, line 32) wherein the protective layer comprises polyacrylamide (Column 12, lines 13-20) and the biomolecules are affixed by electrophoretic resolution using "well known" methods (Column 13, lines 36-40) but they do not specifically teach the protective layer comprises poly-l-lysine. However, electrophoretic resolution on polyacrylamide

comprising poly-l-lysine was well known in the art at the time the claimed invention was made as taught by Heller et al (Column 17, lines 54-65). Specifically, Heller et al teach a similar method wherein biomolecules arrayed and affixed to a polyacrylamide protective layer (Column 5, lines 3-8) wherein the surface of the polyacrylamide is functionalized with poly-l-lysine to thereby provide for covalent attachment of biomolecules to the surface (Column 18, lines 5-10). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the surface modification taught by Heller et al to the polyacrylamide surface of Shiraishi et al to thereby provide for covalent attachment of the biomolecules. One skilled in the art would have been motivated to covalently attach the biomolecules of Shiraishi et al to thereby provide stable, specific and localized biomolecule binding for the expected benefit facilitating detection and analysis of the biomolecule and its interactions. Shiraishi et al. teach the biomolecule is labeled and they teach providing the label by known methods (Column 13, lines 26-40) but they do not specifically teach labeling the fixed biomolecule by hybridization with a labeled biomolecule. However, labeling a biomolecule by hybridization with a labeled biomolecule was well known in the art at the time the claimed invention was made as taught by Davis et al. Specifically, Davis et al. teach hybridizing a labeled biomolecule with a biomolecule fixed on a support (page 85).

Response to Arguments

11. Applicant comments that in view of the previous comments and the amendments, Shiraishi does not render obvious the claims. Applicant further argues that Shiraishi et al in view of Davis et al and Heller et al render the obvious the invention of Claim 20. The arguments have been considered but are not found persuasive for the reasons stated above.

12. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

13. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
July 15, 2003